Privacy & Security Policy Workgroup Draft Transcript March 25, 2010

Presentation

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

Good afternoon and welcome, everybody, to the Privacy & Security Policy Workgroup. This is a federal advisory workgroup, which means there will be opportunity at the close of the call for the public to make comment. And let me do a quick roll call. Deven McGraw?

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Rachel Block is coming in a little later. Latanya Sweeney? Gayle Harrell?

<u>Gayle Harrell – Florida – Former State Legislator</u>

Here.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u> Paul Tang?

<u>Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO</u> Here.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u> Mike Klag?

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean Here

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u> Judy Faulkner?

<u>Judy Faulkner – Epic Systems – Founder</u>

Here.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

John Blair? Paul Egerman?

Paul Egerman - eScription - CEO

Yes, here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dixie Baker? Paul Uhrig? Dave Wanser said he could not make it. Kathleen Connor?

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u> Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Laurel Stein? Terri Shaw? John Houston? Joyce DuBow?

<u>Joyce DuBow – AARP Public Policy Institute – Associate Director</u> Here.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u> Mike DeCarlo for Justine?

Mike DeCarlo - BCBS

Here.

Judy Sparrow - Office of the National Coordinator - Executive Director

Connie Delaney? She said she was joining late. Marianna Bledsoe?

Marianna Bledsoe - NIH - Deputy Associate Director

Here.

<u>Judy Sparrow - Office of the National Coordinator - Executive Director</u>

Peter Basch? Adam Green for Stu McAndrew?

Adam Green - HITSP

Here.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

And, I think on the line from ONC, Jodi Daniel, Sarah Wattenberg and Joy Pritts. And, we also have Alison Rein and Melissa Goldstein, two of the presenters. Anybody that I left off?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u> Yes, this is Dixie. I just now called in.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

Oh, good. Hi, Dixie. Okay, we're ready to begin. Deven, I'll turn it to you.

Deven McGraw - Center for Democracy & Technology - Director

Okay. Terrific, Judy. Thank you very much. Again, another reminder that this is a public call and so therefore, folks should do their best to try to identify themselves when speaking. I think we have a pretty ambitious and very interesting agenda today. We're going to start by looking at the revised recommendation that I sent out based on our last discussion about direct one-to-one exchange by eligible professionals and hospitals for stage one criteria and whether there ought to be additional consent or authorization requirements beyond those that otherwise would apply in law or that entities might impose as a matter of policy. That's what we're going to talk about first.

Second, I want to bring up some things that Paul Egerman brought to my attention in the temporary certification rule regarding how ONC proposes to certify the EHR modules, which are maybe best characterized shortly as component parts that one could pull together in order to meet meaningful use versus buying a complete system and questions that have arisen about how the security criteria in the IFR would apply to those modules. The comment period for that is a brief one given the time circumstances and needing to roll this out. So if we wanted to make any comments on that as a workgroup we'd need to sort of deal with that promptly, because they're due on April 9th.

Then we'll spend really the bulk of the discussion talking a little bit about the paper on consent options that was circulated to the public yesterday. We have the two authors of the paper with us on this call to answer questions and I think this will really be the beginning of our discussion about what beyond the recommendations we settle on today we might want to do with respect to consumer choice or consumer preferences with respect to health information exchange.

That's sort of the order that we're going to tackle this in today unless someone has a strong objection about that. Okay. Hearing none and this is not a shy group we will move right into the discussion of the revised recommendations. This is my best attempt to capture the discussion that we had in the last call. It starts out with some framing comments about the importance of privacy and security, as well as the concept that a comprehensive set of protections is needed and consent is really one piece of that and that there are a whole host of other decisions that are going to have to be made from a policy standpoint in order to ensure public trust.

Then we get to the actual recommendation and again, this was my best attempt to sort of capture where I thought we had landed on our last call, which is that when an EP; and that stands for eligible professional under the meaningful use rules; or a hospital is engaging in direct, one-to-one exchange in order to meet the stage one criteria for meaningful use no additional consent/authorization requirements should be imposed beyond those that otherwise apply under state or federal law. There are a couple of assumptions or areas of explanation here. It assumes a direct exchange model without an intermediary or if there is an intermediary what the intermediary is doing is merely facilitating the transfer and either isn't retaining any individually identifiable health information or accessing it beyond what they would need to do in order to facilitate the transport because when those intermediaries do more is a question that we want to dive into and get into some more detail on in subsequent calls. Then there is just a note that NHIN Direct, which is a project that will draft specifications and services for one-to-one exchange is an area that would be addressed by this recommendation on one-to-one exchange.

We also note here; I heard very strongly from folks on the call that notwithstanding that at this stage we wouldn't be recommending any additional consent requirements for one-to-one exchange for stage one of meaningful use. Nevertheless, certified EHR technology should include technical features that assist providers and hospitals in managing consent laws and patient preferences because whatever we do, they exist today and eligible providers and hospitals are going to have to comply with them and the technology should enhance that and address that.

Then this last bullet here, again, explains that our sort of next step in this is to look at where those transport facilitators or intermediaries, whatever we want to call them, if we can come up with a better term, where they actually do have access to data in some way that's beyond the transport facilitation. What we might want to put into place from a consumer preferences or consent standpoint beyond that, again, noting all along that while we're focusing on consent in this particular set of conversations we do so with an understanding that there are a whole host of other policy issues that we're going to need to grapple with, including transparency.

Then I won't repeat the bullet points that are sort of the rationale for why we came to this. I won't repeat them all. I mean generally we think that the one-to-one direct exchange for the activities that are required in stage one is covered by existing law today. It leaves the data holder in the seat of the decision maker about how much data flows and whether data flows. It's, in many cases, consistent with what patients expect. That's sort of the general rubric of the rationale there.

I'm going to stop because I want to hear from the workgroup about what they think of this, whether I phrased this right, whether there's something I've missed.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

Deven, this is Kathleen. I really like what you did here. I just was under the impression that it would be very clear that the meaningful use would be what was allowed under HIPAA or under HITECH and that was what would put the rubrics around what the sender, as the decision maker, would be doing and it's not entirely clear to me that that's what's covered here because when I look at the criteria under the IFR there are several meaningful use exchanges that are not clearly; and maybe I'm just misunderstanding it; clearly covered under HITECH or HIPAA. For example, sending to PHRs. To what extent does the patient have control over which PHR it's going to be sent to? Are there other, when there's this discussion about sending, under the particular criteria; and I did just mail it to you; I should have sent it to the group; but there's a criteria about exchanging with patient authorized organizations and the objectives, but when you look at the criteria it just says organizations and it's not clear what those organizations are and whether HIPAA would apply to the ... minimum necessary to

I thought we could see if it would be possible to clarify that. That would be great. Or at least say what your intentions are or the workgroup's intentions are with respect to that.

The other thing that I wanted to bring up is I saw and heard on yesterday's discussion that NHIN Direct is going to be possibly using something called the National Information Exchange Model and I'm not sure that that model will support some of the current abilities to convey consent and authorization that have been being developed by some of the health standards organizations. I thought we probably need to take a look at that because we'd want to ensure that current consents and authorizations could be supported under a ... kind of standard in NHIN Direct if that's the direction we're going. Thank you.

Deven McGraw - Center for Democracy & Technology - Director

Thank you, Kathleen. What I remember from the discussion is that I think initially we had thoughts about limiting this to just when there is exchange for stage one of meaningful use with other HIPAA covered entities and then realize that at least with respect to the public health authorities that we couldn't necessarily make that provide though. Then of course, HIPAA covers, arguably, the transport of data into a patients PHR, for example, that that PHR may or may not actually be covered under HIPAA, but the meaningful use criteria of giving patients access to their data or sending them a copy by sending it to the patient's PHR per that patient's request, sort of one side of it's covered potentially by HIPAA, but the other side of it is not. But always, such a transaction would occur only if the patient had consented, so one could argue that that piece of it is already covered in the law.

So in other words, I'm struggling a little bit here with how to represent your concern in the recommendation, because given that the sort of universe of recipients under meaningful use might not themselves be covered entities under HIPAA, but certainly the activities where the data exchange initiates, which is with the EP or hospital any time they would be able to send data for any reason whatsoever it would have to be HIPAA compliant and state law compliant.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

Right, but then there is some question; and it's even raised in ARRA; about whether there is a need to revisit the parameters around exchange and sharing data under operations. When I see a term like the provider will send to organizations it's not entirely clear what the limits of the purpose of use are.

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Right.

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u>

I'm a little concerned and I think either we should note that and ask for clarification or somehow make it clear what the intent of the workgroup is. Thank you.

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

Deven, this is Dixie. I did, even though I wasn't able to be there, listen in to yesterday's meeting. I personally don't think what the transport is, whether it's NIEM or TLS or whatever, TLS over the Internet, direct Web portal or whatever, I don't think that's relevant at stage one. I think that you've captured it precisely here, Deven. It's that for stage one what's required is exactly what's in the law. They have to protect the link and all of that, but as far as consent, where they have to consent under state and federal law, they still have to consent under state and federal law for stage one meaningful use and there's no difference. So I don't think that NIEM or NHIN Direct or whatever is relevant to what we're trying to say here.

Jodi Daniel - ONC - Director Office of Policy & Research

This is Jodi Daniel. If I can respond to the earlier comment about concern about the scope or the purposes of the disclosure, it does only talk about stage one meaningful use, so there are limited types of exchanges there. It's not all of healthcare authorizations. There are some public health disclosures. There are some quality reporting disclosures. All of that would be covered and I think, obviously, as permitted under the HIPAA rules. So I'm not sure that we have an issue of the scope of the type of disclosures we're talking about because the recommendation is limited to stage one criteria for meaningful use. Does that help at all?

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Better said than I did it. I agree with you.

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u>

I'm looking at the wording in the IFR and it would be great if it was narrowed in the actual statement of the criteria that this was –

Jodi Daniel – ONC – Director Office of Policy & Research

But can I – I'm sorry, Kathleen. I didn't want to interrupt you. Please keep going.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

No. I'm just hoping that, Jodi, I was trying to connect with what ... was saying and what it said in the IFR.

Jodi Daniel - ONC - Director Office of Policy & Research

Yes, although I guess I'm curious as to why you're looking to the IFR as the statement of the criteria versus the meaningful use NPRM where the criteria are articulated with much more specificity.

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u>

Well, maybe that would help and I will look there, but there is this idea of exchanging; that one of the meaningful use measures is their ability to exchange.

Jodi Daniel - ONC - Director Office of Policy & Research

Right.

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u>

It's kind of vague about who they're exchanging with and for what purposes.

Jodi Daniel – ONC – Director Office of Policy & Research

I have a suggestion that we could, even as we sort of get somewhat comfortable or comfortable with the language here, that we could take another look at those meaningful use criteria and make sure that we're not missing something that concerns us. I mean I want us to be comfortable with where we're going and even though we won't always, as a workgroup, be able to reach 100% consensus, I want to always try to do that when I can.

W

Let me ask a question. Is it possible that in the recommendation where it says, "One-to-one exchange to meet the stage one criteria for meaningful use," if we said, "As set forth in the NPRM," or something like that to limit it to the more narrow criteria that Deven was talking about? Does that help?

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

I think that it would be great if we maybe off-line just take another look at the criteria and just make sure that this captures what is intended, which is what's allowed under HIPAA today I think is what your intent is or the workgroup's intent is.

Mike DeCarlo - BCBS

Can you give us a reference, Kathleen, to what part of the IFR you're looking at here, a page number or section?

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

I will cut and paste the specific areas and send it to the group so you can find it. Thank you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thank you, Kathleen. We've got one more call before the April Policy Committee meeting to finally wrap this up and so, number one, Jodi, I actually think your suggestion is a good one; that we're talking about what's in the NPRM. If that wasn't obvious to folks, that certainly was my intent, but it doesn't hurt to be very specific that that's what we mean. We can take this time just to make sure that it is the narrow set of criteria that at least some of us have assumed and that we haven't missed anything. Let's take some time to do that because, fortunately, this time we have it.

<u>Terri Shaw – Children's Partnership – Deputy Director</u>

This is Terri Shaw. I just wanted to, first of all, say hello. I joined late. I apologize.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

That's okay. Thank you. We're glad to have you.

<u>Terri Shaw – Children's Partnership – Deputy Director</u>

And also just to make sure that I'm understanding things correctly and that we're all on the same page, that in saying this recommendation in this way what we are not saying, if you can do it under meaningful use stage one it doesn't require consent.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

No.

Terri Shaw - Children's Partnership - Deputy Director

What we are saying is it doesn't require anything in addition to what otherwise would apply, which, in some cases will mean either consent or even more specifically authorization.

Deven McGraw - Center for Democracy & Technology - Director

Right.

Terri Shaw - Children's Partnership - Deputy Director

Okay. I just want to make sure that we're all on the same page.

<u>Deven McGraw - Center for Democracy & Technology</u> - Director

That is consistent with my understanding of where we are.

Terri Shaw - Children's Partnership - Deputy Director

Great. Same here. Then I personally am comfortable then that the distinction that we're making here is that for that exchange in this context we're basically just saying existing law, whatever that may be and it will vary state-by-state.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right.

Terri Shaw - Children's Partnership - Deputy Director

That works.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Terri?

Terri Shaw - Children's Partnership - Deputy Director

Yes, that works for me.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. Great. I thought for a minute that we lost you. Does anybody else have any comments on this?

Paul Egerman – eScription – CEO

Yes. Deven, this is Paul Egerman.

Deven McGraw - Center for Democracy & Technology - Director

Hello, Paul.

Paul Egerman – eScription – CEO

I have a question about the second bullet in the recommendation. Perhaps it's just phrasing, but I don't understand who we're making a recommendation to and what the recommendation is. Is this a recommendation relating to stage two certification? Is this something that we expect the Standards Committee to act on? I don't quite understand what's intended by the second bullet.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Well, I didn't phrase it with specificity, Paul, and we could get more specific if we wanted to. I mean I think we all understand that the door for stage one criteria is shut, so we would definitely be talking about stage two if we were looking to do it, have it be part of certification. I did use the term certified EHR technology, so I think that's right. We could specify stage two. We could provide a priority to the Standards Committee or ask the Policy Committee to endorse a priority for the Standards Committee to establish technical features. We have Dixie on the phone. I think she can opine on that. I mean I was just reacting to what I've heard on numerous calls that we've had with this workgroup, which is to say folks want the technology to be able to honor these consents and help providers and hospitals manage them. Manage is my term. It's not maybe the best one technically, but I think you all get what I mean and if we want to propose something much more specific then I think we should do that.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

I didn't understand that's what you were saying at all in this bullet.

Deven McGraw - Center for Democracy & Technology - Director

Good thing we have these phone calls.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Privacy and security protection is not equivalent to consent management in any sense. If you want to say that we want to recommend that priority be given for stage two to including in the certification criteria consent management features I think that's what we should say.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. I'm not adverse to that at all. Clearly, that was my intent, but as with all things standards related, Dixie, I am always better off when I ask you to help me with the phrasing of it first.

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

I'll be happy to send you a bullet or send everybody a bullet -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. If you can send it to everyone that would be -

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Sure. I'd be happy to do that.

Paul Egerman - eScription - CEO

Deven, maybe as Dixie is creating the bullet the recommendation I'd make is to be very clear that what's happening, I think, is that the Policy Committee is asking the Standards Committee to do something. The only reason I say this is otherwise I'm afraid if you pull this sort of bullet out like this it sounds nice, but no one was instructed to do anything, so nothing will happen.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay.

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

I didn't have any meaning. I just thought that was kind of motherhood and apple pie.

Paul Egerman - eScription - CEO

Basically, Dixie, that was my question. Is this motherhood and apple pie or is somebody supposed to do something? If so, who is it and what should they do?

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Okay. In my ... I'll send to Deven because she has the distribution list, I'll make sure that it says ask the Standards Committee.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Are folks comfortable with that?

Mike DeCarlo - BCBS

Deven, another way to sort of look at it is an objective is consumer engagement in the process, so the use of a qualified or a certified EHR for the purposes of meeting that objective would be to use an EHR that had the capability to manage consents and authorizations, as you phrased it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Deven, this is Paul Tang. One, I think it's an excellent idea or suggestion to make it clear which pieces of our recommendations are targeted towards, let's say, the Standards Committee. I wonder if in the course of saying this we're saying managing consent laws and patient preferences should we have drilled down and say what do we mean by managing consent and patient preferences. Actually, that's even one of our eight things we're supposed to do.

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Right.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So do we have to finish the job before we hand it over?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

Oh, that's a good question.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Because your third bullet actually starts even talking about the "additional consent requirements," so what is it that we're going to hand over?

Deven McGraw - Center for Democracy & Technology - Director

Well, I mean notwithstanding that this is a policy area that we're still discussing, we do have laws and requirements in this regard already on the books. You know HIPAA requires patient authorization in some circumstances. The substance abuse treatment rules under part two require patient consent and an even greater set of circumstances. There are state laws that apply here that either apply across the board or are specific to certain types of data. So we don't have a policy vacuum on this issue today. We actually do have providers, who have to comply with the law today and to what extent should there be technical features built into the systems.

Now, if we wanted to be more specific about exactly what the systems would have to honor in terms of the complete universe of policy in this regard then yes, we would wait, but we do actually have law already.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

But we don't. Paul has got a good point. The law doesn't in all cases specify the specificity that the consent needs to apply to or authorization as the case may be. Maybe what we want to do, since this is the framing part of the document, is establish for ourselves a priority for refining and specifying requirements for consent management in phase two.

Paul Egerman - eScription - CEO

I agree with what Dixie just said. It sounds to me like where we are with this is this is really our priority. We need to think through all of that legal material that you just mentioned and say with greater clarity what are the areas that we want included in this and then hand it to the Standards Committee; otherwise I

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

... level of granularity like the opt-in/opt-out versus sections, all of the topics we've gotten into before.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right. I like that idea. I think that's fair. I think those are very good points. Are there other workgroup reactions?

W

So basically are what we're saying is that we should hold off until we have a comprehensive approach to this?

M

No.

Paul Egerman - eScription - CEO

No. I think for stage one, stage one is basically implement HIPAA. As we just sort of pointed out to the world, it isn't completely implemented. So as we said, implement HIPAA and there can be an enumeration of the things that providers would need help with to make it less of a burden for them and that can go off to the Standards Committee. We do have, as our charge, to work on other things; ARRA provides some and we raised some other issues that we'd like to deliberate on and hopefully include in stage two criteria.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thank you, Paul. I think I heard that and a slight nuance, which is that we need to be more clear about how we want consent to be honored from a policy standpoint before we can give a directive to standards to establish the technical standard. Is that it?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

Yes.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay.

Paul Egerman – eScription – CEO

Sure.

<u>Kathleen Connor – Microsoft Health Solutions – Principal Program Manager</u>

I think that I mean hopefully this paper will illuminate some of the issues, but I think it looked at what is actually being; I haven't read it all of the way through, but approaches for dealing with consent by health information exchanges today. I think there's another need to look at what the laws actually require –

Deven McGraw - Center for Democracy & Technology - Director

Right.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

It may be that we have to acknowledge certain levels of granularity and choices about providers or purposes of use ... laws outside of HIPAA that may set the boundaries of what we send over to the Standards Committee and say, "This is the capability that needs to be supported. What's out there that can do it in stage two or three?"

Deven McGraw - Center for Democracy & Technology - Director

Right.

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Yes. That's what we're saying.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. That makes sense.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Do you want me to do a bullet that says that?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Well, I would love for you to do a bullet that says that, Dixie. Thank you.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Since I signed up for a bullet I may as well do a bullet.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Very helpful. Thank you.

M

Basically though, of these three bullets the last two bullets are really decisions about what we, as a workgroup, will be focusing our short-term attention on.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, signaling future work.

M

Definitely. Yes.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Yes. That's good -

M

Yes. So it's sort of like workgroup direction or workgroup focus or something like that is really the title for the last two bullets.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. Good point. Okay. Anything else?

W

There is a little one that I'm noticing out of the NPRM. I thought of it earlier. There's really no; maybe I'm mistaken on this; previous legal or regulatory experience around sending people preventative and follow-up care reminders. If they're doing that electronically and it's something that's sensitive there's nothing in here that says this patient has any control over how that comes to them. I mean if the family shares an account, an e-mail account and some sensitive reminders come over that could be a problem. Can we put that just sort of as a placeholder to think about?

Deven McGraw - Center for Democracy & Technology - Director

Yes, although I thought that that was per patient request about how that got sent.

W

It is per patient request. Yes. I agree with you, but that might require certain kinds of actions on the part of the provider to protect that information that they may not know about or understand how to implement, so –

M

Presuming we're moving beyond just a simple yes I want them/no I don't want them.

W

Right. It's, for example, sensitive services related to treatments for sensitive conditions and things going on. Yes. I just think we should take a look at that and maybe think about what it would require from a technical perspective.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I don't disagree at all. We have it so noted. Other comments before we move on?

Terri Shaw - Children's Partnership - Deputy Director

I think that last set of discussion, I agree we should follow up on that. I also think it highlights when ... HIPAA rules, for example, on right to request restrictions, for example, that would apply and we're saying have to be incorporated even in this one-to-one exchange situation.

Two, I think this is an illustration of what I'm hoping we're getting at with our recommendation on uses of technology to support privacy protection essentially, because what I'm envisioning is requiring being built into EHR certification and, frankly, into HIE systems over time some sort of rules engine, if you will, that helps to flag this type of stuff needs to be handled in this way so that that becomes more automated and more protected than perhaps is even done currently.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Eventually what you really want is for that rules engine to contain rules on how to translate the consents into access control.

Terri Shaw - Children's Partnership - Deputy Director

Exactly.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Yes and I'm starting a series of briefings about technology that supports consent management in general specifically focused on standards. Anybody is welcome to join those. Those sessions will address exactly what you're talking about, how that translation occurs.

<u>Terri Shaw – Children's Partnership – Deputy Director</u>

Could you let us know when those will be?

Deven McGraw - Center for Democracy & Technology - Director

Yes. You should have actually gotten a notice from Judy –

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

That was the first one.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

About the first one, which is April 1st, right, Dixie?

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Thank you very much.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes.

Terri Shaw - Children's Partnership - Deputy Director

Yes, I did get that. Thank you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thank you, Dixie. I think that's going to be really interesting.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Good. I think so too.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I'm fully prepared to be lost by within half an hour of discussion, but it should ultimately be very helpful. Any other comments?

Okay, I want to move to the temporary certification program rule of which Paul Egerman drew this to my attention so, Paul, I'm really glad you're on the phone and it will be great to hear from you and Dixie and others, who may be more familiar with this language and may have thought about whether there are some additional comments to make on ONC's approach. But as I mentioned in the beginning of the call, ONC has outlined a possible approach for dealing with the certification of EHR modules with respect to the security criteria that are in the interim final rule, because in some cases it might not actually be appropriate for the module to have to meet all of those security criteria, depending on what function it fulfills.

Paul, since you're probably more familiar with this I'm going to put you on the spot here and see if you have any additional thoughts that you want to share on this. Again, the comment deadline is very short on this. It's nothing that we would have time to pass through the Policy Committee, but if folks had a set of substantive comments that they wanted to make on this we could work them up and have them come from the Privacy & Security Workgroup.

Paul Egerman - eScription - CEO

All right. Thank you, Deven. It's Paul Egerman. Let me just comment on a couple of things first. To explain this NPRM, this NPRM is about the certification process, which is sort of like who can do the certification, how they do testing, where they do testing. It covers everything except what is actually tested, so the actual content and what is tested is in the IFR. This is all very much process oriented.

I also want to clarify something Deven just said, which is -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I knew I'd probably mess something up.

Paul Egerman - eScription - CEO

Which is my understanding from the last Policy Committee meeting; it is that workgroups cannot make recommendations to NPRMs. They have to be approved by the entire Policy Committee; however, the Certification Adoption Workgroup will be making a series of recommendations and so Paul Tang will arrange some telephone call or e-mail process or something prior to April 8th or April 9th so that if this workgroup wants to make a recommendation on this topic then it will have to be approved through that mechanism by the entire Policy Committee, but there will be a probably short meeting or vehicle to make that happen.

Now, the content of what this is all about, as I say, it's process oriented and it sort of describes a little bit about how modules will get tested and certified related to privacy and security. It sort of walks through a few cases, like I said, part of like a pre-coordinated and integrated bundle. If they're intended to like stand alone by themselves and be autonomous. I think there's also an example of if it's by itself for privacy and security function in terms of how that is going to work. It basically states that I think the testing process, testing and certification is sort of dependent upon the module itself and sort of the like the context in which that module is intended to be used. So it goes through a fairly long discussion of that and says we request public comment as to whether those additional alternatives and also whether or not the circumstances it describes are correct.

The reason I forwarded this all to Deven is that was one of the topics I had heard discussed in this workgroup previously is how do you do some of these enterprise privacy and security things when there are modules. Well, here is the opportunity to see how ONC is proposing that to be done and the opportunity to comment on it ... people ... this is good or not good or if they have other, alternate suggestions.

Jodi Daniel – ONC – Director Office of Policy & Research

We really would love your input on this because this is really hard.

Paul Egerman - eScription - CEO

Yes.

Jodi Daniel - ONC - Director Office of Policy & Research

So insights or thoughts on this would be greatly appreciated.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thank you, Paul. Thank you for the correction on the process. Of course, you know -

Paul Egerman - eScription - CEO

It was just a clarification -

Deven McGraw - Center for Democracy & Technology - Director

Yes. I mean there's nothing -

Paul Egerman – eScription – CEO

You had it exactly right except for one word.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

As a workgroup we couldn't do it if we felt ... wanted to as a group of citizens submit a comment. We could do that, but yes. I mean I'm glad that there is a process that's been set up to allow us as a

committee to be able to respond, because I think that's much more effective and that all totally makes sense to me.

At first blush in looking at this I did not – it actually seemed like a very reasonable approach from a process standpoint to dealing with modular certification where, depending on what the module does and how it's paired up with other modules in order to get the provider or hospital to meaningful use, as long as at the end of the day all of the criteria are accounted for that's probably the most important, so my first gut reaction was that I didn't have anything to add to what seemed like a reasonable approach to dealing with a difficult problem, but maybe. I don't know if folks got a chance to read this. We had an awful lot of reading material for our call today. Did anybody have any particular reactions that they want to share at this point?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

About the?

Deven McGraw - Center for Democracy & Technology - Director

About the EHR module certification approach that's outlined in the temporary program rule.

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

I haven't finished reading that rule.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. Well, why don't we do this? I think folks, please take some time to read this. Unfortunately, you'll need to do it quickly. Our next call as a workgroup is on the 8th and, as Paul Egerman just explained, the mechanisms for being able to comment on this are really going to be close to being done by then if not finished. So what I would ask is for folks to take some time to read at least the excerpts that I sent you even if you're not interested or if you're not going to read the whole certification rule and let me know by e-mail if there are some points that you want to press or something that occurs to you and we can either set up a smaller call of interested parties or we can just pass that along to the certification workgroup.

Paul Egerman - eScription - CEO

Deven, that's excellent. The observation I'd make is picking up on what Jodi said. I think the very fact that it says here, "We request public comment," sort of suggests that ONC knows that this is important and they want to make sure that they're getting it right. So I think people spending a little time and going through this and making sure that this is a good way of doing it, I think that would be good.

The other comment I'd make is that it really doesn't have to come to the certification group. It could be a letter from this workgroup. I think that would be the best place for it to be and if you decide, as you initially said, Deven; and I tend to agree; that this looks good, a formal letter that says you reviewed it and you're comfortable with it; that has value to ONC.

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Right.

Paul Egerman - eScription - CEO

So that would be a good work product. I think you need to come to that conclusion if that's your conclusion, prior to April 8th.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes.

Paul Egerman - eScription - CEO

Yes. I mean I think you need to set a deadline, like ask people to review it and get their comments to you like Monday or Tuesday or Wednesday of next week so that there's time to draft a letter and Paul Tang can set up his phone call.

Deven McGraw - Center for Democracy & Technology - Director

Okay. That's a very good idea, Paul. So why don't I ask folks to send me any thoughts or concerns that you have about the approach that's outlined. Again, we sent you an excerpt, so if you don't want to go through the whole certification rule you really don't have to for this purpose. If you do so by close of business, and that includes West Coast time, on March 31st, the end of March does that sound like a fair idea? Then otherwise also let me know, because I'm inclined to tell OCR that we think this is a reasonable approach for moving forward, but I know I've read it and other folks haven't, so I guess I'm ask two things here. Let me know if you have something that you want to raise, either a concern or an idea; and secondly, let me know if you're comfortable with saying assuming that no concerns or different ideas are raised that we would send a letter that this seems like a reasonable approach.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

Deven, just to make sure that I have the right stuff, I have the PowerPoint, the agenda, things that are called preliminary framing comments and then another thing called Web Privacy and Security Certification ... with that, plus the half-inch thick thing.

Deven McGraw - Center for Democracy & Technology - Director

Yes.

<u>Judy Sparrow - Office of the National Coordinator - Executive Director</u>

Do you mean read, by the excerpt, you mean everything but the half-inch thick thing?

Deven McGraw - Center for Democracy & Technology - Director

No. I was specifically talking about the three pages on EHR modular certification. I can resend it.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, because I might -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

You don't have to go searching for it amidst what are probably mounds of e-mails in all of your inboxes.

W

Judy, it's the one that you mentioned that starts, "When privacy and security certification criteria apply to FHRs."

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>

That's the one? Okay.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

It's only three pages.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay.

Paul Egerman - eScription - CEO

I'm sending it to you right now, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

No, I have it. It's the one that starts page 11.342.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes.

Paul Egerman - eScription - CEO

Yes. That's correct.

<u>Judy Sparrow - Office of the National Coordinator - Executive Director</u>

Okay. Great.

Peter Basch - MedStar Health - Medical Director

Deven?

Deven McGraw - Center for Democracy & Technology - Director

With reference to the Federal Registry. Yes?

Peter Basch - MedStar Health - Medical Director

Deven, hello. It's Peter. I called in before, but somehow I was put on a muted line, so I was speaking and couldn't figure out why you guys couldn't hear me. Do you want to hold off on comments if people had comments and just take them in writing?

Deven McGraw - Center for Democracy & Technology - Director

If they are - well ...

Peter Basch - MedStar Health - Medical Director

I'm fine with that. I was just trying to make a comment as you were talking about this, but I'd be happy to send it in.

Deven McGraw - Center for Democracy & Technology - Director

Yes, why don't you send it in? Because I just have a feeling that we don't have enough people on the phone who've had a chance to read this even though it's pretty short.

Peter Basch - MedStar Health - Medical Director

Yes. It's a three-pager entitled PS Cert. Criteria.

Deven McGraw - Center for Democracy & Technology - Director

Yes.

Peter Basch – MedStar Health – Medical Director

Yes. Okay. I'll send it in.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. Thank you, Peter.

Peter Basch - MedStar Health - Medical Director

All right.

Mike DeCarlo - BCBS

Deven, I had a recollection having listened to Dixie's IFR policy and security committee that her committee did discuss this in a general way, this issue of trying to apply privacy and security requirement evaluations to the EHR modules when they were looking at the IFR and developing comments. I can't remember if they actually put that in their comments, but I have a recollection that they did discuss it. It might be worth looking at that discussion through their transcripts as well to see what sort of comments were made at that time, but it was discussed in a more generic sense than what's been laid out here in the certification

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Okay.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Well, I can tell you what we recommended and I was just trying to figure out in my brain how it would actually translate into this, but our concerns were that if you had a module, if every module incorporated security features to comply with the security and privacy certification criteria then it would be impossible to have enterprise wide enforcement of a uniform policy.

On the other hand, if you had certain modules that were security modules because they spoke to specific security criteria, which is how they define modules, then you had no way of assuring that the other modules would use that module as their security service. Do you know what I mean? So that's the dilemma.

So what we end up recommending and, as you brought it up, I would say this was our primary recommendation regarding the IFR and their primary concerns. What we ended up recommending was if a module were submitted for certification, presumably a health module, health related module, then that module would need to treat every security and privacy certification criterion as addressable in the same sense that HIPAA defines addressable. If I were vendor X and I submitted a CPOE module, let's say, then I would need to go down that list of six or seven criteria, security certification criteria, and say is this applicable to my module and the intended environment based on its specification and its intended environment? Is that applicable? If no, I say no. If yes, how will this criterion be addressed and how am I assuming it will be addressed in the operational environment and include that as part of the certification?

So my question as I started reviewing the NPRM is how that could really be operationalized in that model. That part I haven't figured out yet.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right. Well, I mean it seems to me from reading the proposed approach that ONC has here, that they've followed similar; that they're setting forth something that is similar to what you just said, but you should definitely read it.

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u> Okay.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Because it may be that we're talking about two different things.

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Yes. I definitely started it. I just -

Deven McGraw - Center for Democracy & Technology - Director

Yes.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

... look at this excerpt you sent.

Deven McGraw - Center for Democracy & Technology - Director

Yes. No. So I think it makes sense given that folks had a lot to read to prepare for today that we give people a chance to weigh in by e-mail and see what we are able to pull together in an e-mail fashion.

Paul Egerman - eScription - CEO

I'd just say what would be particularly helpful, Deven and Dixie, would be also if people looked at this and they thought is there any circumstance that this really doesn't cover.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right.

Paul Egerman - eScription - CEO

That's one of the key questions: Is there some circumstance that you can think of that this approach – the approach seems right to me, but maybe there's something I'm not thinking of that it doesn't cover, so that's a key question.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Exactly the same reaction I had. I was like, "Wow, those are good ideas." What's missing? Great. Very helpful.

Okay. Let's move on then now that we have a plan for that piece. Let's move to the discussion of the white paper that ONC released yesterday. I know we have the two authors on the phone call. I suspect we have workgroup members, who have made varying degrees of progress in reading it. I, thankfully, have been able to get through all of it at least once, but I think it makes sense to turn it over since our authors have some slides, so I'll turn it over to Jodi, unless you tell me I should just turn it directly over to Alison and Melissa. Just let me know what's next. We're ready for it.

<u>Jodi Daniel - ONC - Director Office of Policy & Research</u>

Okay. Great. I have Alison here and Melissa is on the line. We were hoping; and I'm going to be very brief; that this would be a helpful sort of transition to the more kind of in depth discussion I expect that we're going to have on consumer choice as it relates to broader health information exchange beyond the limited recommendation that we were discussing in the earlier part of the call.

Really, as I mentioned the last time, the whole purpose of this was to have the GW folks who worked on this try to really tease out the different issues, stakeholder groups, perspectives, some real world examples of how things are working and look at the issue of consumer consent from a variety of different perspectives so that you all had and we, ONC, had information we needed in order to really think through this discussion and come to some recommendations on policy in this area. So I'm going to not talk for too long. I'm just going to turn it right over. I don't know, Melissa, if you want Alison to take the lead or if you want to take the lead.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

Alison, if you would like to take the lead, go ahead and I will chime in.

All right.

Jodi Daniel - ONC - Director Office of Policy & Research

That sounds good.

Alison Rein - NCL - Assistant Director Food & Health Policy

So on behalf of the entire research team behind this paper I'd like to apologize for the length. Already a number of people have referred to the half-inch thick document, so we're sorry, but as Jodi mentioned, this was really intended to be a level setting document that covers a variety of different issues that come up and are surfaced when you discuss the issue of consumer consent for electronic exchange. We got a lot of it in there, hopefully not too much. So that is the explanation.

I want to mention Melissa and I were the lead authors, but we had a ton of great researchers from the four folks who are listed and with me in the room actually is Scott Weinstein, so if we run up against a particular question he may be called upon and that's the voice you'll hear.

We thought it would be helpful to start by just outlining a little bit more about what this paper is intended to do and then go into what it's not intended to do. We wanted to identify the core issues and challenges associated with the primary consent models for electronic health information exchange. We wanted to get out there a set of core definitions so that we could all hopefully be speaking the same language and point out a number of the stakeholder perspectives in areas where they might converge and diverge.

We wanted to explore the consent models that are actually applied in a small subset of electronic exchange efforts and learn more about the rationale for why they proceeded in certain ways or didn't.

We also considered and analyzed some of the possible consequences associated with different consent approaches. We did not intend to do a comprehensive analysis of the electronic health information landscape and we did not attempt to perform a comprehensive review of existing consent models as they are applied in active electronic exchange efforts, so we were trying to surface important issues through the use of examples, but not do a complete survey of the landscape.

We certainly were not trying to be directive or suggest that there is a single, simple answer. The more we did research on this paper and wrote the more we realized how thorny it was, so we would never suggest that it's easy.

What's covered: We have the five core models that I alluded to. We talk about granularity and its relationship to consent. We highlight a number of U.S. and international examples of exchange. In the analysis section and impact of consent models we raise a number of ethical considerations, process logistical and technical considerations, legal framework and stakeholder perspectives. I should suggest here that we already were, as I mentioned, in a very lengthy document and so we had to sort of superficially cover a lot of ground. If there are areas where the group in reading this finds that there is a need for more substantive research or clarity on a particular issue we're certainly open to hearing that and I assume that there might be an opportunity to explore that either through this or some other arenas.

Five basic consent models: There are obviously much longer descriptions in the actual paper, but no consent; opt out; opt-out with exceptions; opt-in; opt-in with restrictions. I should note that in the no consent and opt-in models we needed to point out that it's possible that somebody could in any of those be automatically put in to how their information flows through an exchange, but then there could be a

distinction where there's a second level of consent for actually gaining access to that information. So that's discussed further in the paper as well, but not obviously here on this slide.

Granularity observations: So there's a much richer discussion of this in the paper, but we carve out four different areas of granularity; type, provider, time range and purpose and data type. The example we have here is that very often exchanges only include certain types of data in order to avoid having to deal with some of the thornier issues and/or because that's the only type of computable data they may have available for exchange.

... by provider: Most often this means that you can have granularity by the provider entity, not the individual provider, although we did find a couple of examples where you could specify at the individual provider level.

By time range: This was less common, but the application where you do see it is in sort of break the glass, so you can have access to this information, but only for a specified time period under these circumstances.

Then by purpose: So you can exchange information for treatment purposes, but if you need to use it for something else then that might not be covered under that consent.

Just a pause here. People may have noticed I'm from New York. I'm rushing through this rather quickly and I want to do that in order to maximize the time we have for questions and discussions, but if at any point either Melissa or any of the other workgroup members want to interrupt and ask a clarifying question, please go ahead and do so.

M

So do you want us to interrupt while you're doing this. If we have observations do you want us to wait until you're all done?

Alison Rein – NCL – Assistant Director Food & Health Policy

Deven, I would actually defer to you on that. Do you have a preference?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

How much time did you reserve for this sort of introduction to what's in the paper?

<u>Alison Rein – NCL – Assistant Director Food & Health Policy</u>

I hope to finish in the next few minutes.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. Let me let you finish then, because that will sort of be a level setting vehicle for folks who haven't had a chance to read through the paper yet and then I'm confident you'll get a whole lot of questions.

Alison Rein – NCL – Assistant Director Food & Health Policy

I'm confident too.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Including a couple from me.

Alison Rein - NCL - Assistant Director Food & Health Policy

We provided here some of the major stakeholder perspectives that we discuss through the paper and sort of a brief overview of what they want and what they'd like to avoid. Obviously, these are generalizations to some extent. We can't purport to know exactly what every particular patient or provider would want, but based on discussions and the literature this is sort of the generalized version of it.

We conducted primary research, so we had a number of phone and e-mail correspondence with folks that were involved in the HIOs that we used as examples in this, some legal consultations, etc. Then the vast majority I'd say was based on secondary research and so we've provided just a list of the types of resources that were used to generate the research that is behind the paper.

Some general observations: We identified a fairly small number of operational exchanges that have, and this is a huge caveat, publicly articulated consent policies. So we definitely acknowledge that most of the examples in here are sort of state based exchange efforts and that is largely due to the fact that we were able to find the information about the consent policies that they'd articulated and the rationale behind that, etc. It would have been, I think, a much lengthier process to try and determine that level of information from other types of exchanges.

We also note that the diversity across exchanges really prevents a great deal of generalization about what does or doesn't work with respect to consent. There's just not a sufficient number and there's, to the next point, not really sufficient evidence yet to know what works and what doesn't.

We did though find that there tended to be agreement that the more information included, and that's both volume and type of information in an exchange, the greater the benefit, perceived benefit, to patients, providers, clinical care, public health and research. We will note that the architecture of the exchange has implications for the feasibility and desirability of certain consent options.

The last one, some recommendations: We didn't feel comfortable given the number of exchanges that we researched and the lack of definitive evidence of what really works and what doesn't with respect to consent to recommend that one consent model would fit all circumstances. We think that there is a lot of guidance needed for contextual assessments here.

We suggest some helpful steps for moving forward. Two of them, the first and the last on this list, really would be to support collaboration across exchanges and systematic provision of information and tools to state HIE grantees. We know that there's a lot of that already planned, so we're encouraged by that.

But we also think that there could be compensatory measures to promote adoption or lessen the short-term cost barriers. We think that there could be development of better evidence base to determine the relative effectiveness and perhaps more importantly, just the impact of the different models in different context and would encourage coordination of a broader policy discussion regarding consumer protection environment relative to consent. So the notion here that surfaced a lot in the paper is that you don't want to overly rely on consent as being the only vehicle for ensuring that you have adequate consumer protection. There are a lot of other contextual policy areas that need to be considered and I know that this group is very savvy in the ways of that thinking, but we just thought that that was an important point to articulate.

I'm going to stop there. I apologize that that was so quick but, Melissa, do you want to jump in and add anything before we just open up the floor to questions?

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

I think questions are good now. I think that's a great general presentation. Thank you.

Jodi Daniel - ONC - Director Office of Policy & Research

Yes. It was very good, Alison. Thank you very much. Paul, it sounded like you had some guestions.

Paul Egerman - eScription - CEO

Well, I had a comment and a question. First, let me thank you. This was a significant amount of material and I probably only read about a third of it, but it is a huge amount of work and I would very much appreciate that. The comment I had or the observation I had is that in reading the first part of the document I think you showed or the author showed a personal bias in the way you discussed direct connection and exchange versus exchanges through a health information organization because every time you would talk about the direct exchange you used the word basic and when you would talk about any kind of other exchange you used the word sophisticated. I'd just say I think a lot of people would take exception to that. It's a minor point. It doesn't have a lot to do with the rest of the paper, but it was a little distracting and I would like to ask if there is a subsequent draft that you review that.

The more substantive question I had gets back to the issue of granularity where you sort of talked about all of these different ways of granularity types, but don't really consider from a consent standpoint I don't think or maybe a better way to phrase it as a question is what about segmentation. I mean is segmentation a type of granularity that you could consider from the standpoint of consent? For example, if you segmented a medical record and you put behavioral health in one segment would you be looking at your consent options in a different way where in an opt-out situation for everything except for the behavior health segment, for example, where maybe opt-in is required?

Judy Faulker - Epic

Can you explain, Paul, what you mean by segmenting behavior health? I can see segmenting, say you have a behavior health physician, segmenting that person's notes, but what else would be segmented?

Paul Egerman - eScription - CEO

Was that Judy?

Judy Faulkner - Epic

Yes.

Paul Egerman - eScription - CEO

I had a feeling that was you. That's a great question and I'm not sure I can answer that correctly, but one way you could approach this issue would be to sort of say we're going to segment behavior health and you're going to decide the answer to the question that you just raised, so it maybe includes the notes, but maybe it doesn't include something else. Whether or not it includes medications I don't know, but you create a sense of a concept of segmentation and then once you've created that I'm just wondering if that's just another option. It's another type of granularity that we could consider because I look at these other things like by data type and I have a sense of where you're coming from, Judy, in asking that question, but these other granularity options also have the same kinds of problems when you try to do it by data type and by provider.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

Can I just jump in here for a second, just to remind folks that in the CCD there is the opportunity to put confidentiality code at the section levels and at the header? At the header level you could be very specific about the data elements that you wish to have segmented or treated differently, so a compliant CCD can support that kind of data segmentation and since it happens on the outbound and doesn't have

to be inside the system that should be at least some comfort to Judy. I don't know, but there is also the ability to reference a consent directive or a privacy policy from the CCR at various levels. Thank you.

Paul Egerman - eScription - CEO

That's helpful, but I don't think that's the same as segmentation.

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

It would tag it as something that needed to be treated differently by an HIE or receiving entity and then, as Dixie talked about before, access ... can be applied.

Peter Basch - MedStar Health - Medical Director

Yes. Paul, I think I understand what you're talking about by segmentation, but maybe you could try and explain it a little better?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Is that Peter?

Peter Basch - MedStar Health - Medical Director

Yes. I'm sorry.

Paul Egerman – eScription – CEO

Well, I mean I'll do my best because it's one of these things that I don't want to pretend to be like an expert on it, but the analogy is that it's almost like you look at the patient's medical record in a manual sense and you consider it like a bunch of documents in a folder. The concept of segmentation is there's, in effect, more than one folder for a patient, so the patient might have a behavior health folder. They might have a reproductive health folder. They could have three or four different folders and so in response to what Judy said, you have to decide what goes into each folder, but in the behavior health folder one of the things that would probably be there would be any kind of textual note about —

Peter Basch - MedStar Health - Medical Director

The best way I could see doing that would be to actually create another patient record and so you are Paul Egerman, but your other patient record gives you a different name and there is no coming together of those two. That way –

Paul Egerman - eScription - CEO

That's problematic from a technology perspective, particularly when you try and have interfaces work and not error out and registration systems actually work appropriately –

Peter Basch – MedStar Health – Medical Director

Yes, I know. I'm saying I don't disagree. It is. But it's the safest way to make sure that if you put in meds, if you have x-rays that are –

Paul Egerman – eScription – CEO

Well, no. That's right. That's -

Peter Basch - MedStar Health - Medical Director

It's the only safe way.

Paul Egerman – eScription – CEO

Well, it depends on what the desired outcome is.

Peter Basch - MedStar Health - Medical Director

Yes.

M

If the desired outcome is that you want to attempt to do something, which I think is actually impossible to do, which is everything that has to do with behavioral health is somehow removed from the medical chart, I'll tell you from my perspective as a primary care physician it's impossible because behavioral health issues touch upon all medical disease and you can't really sweep all of that out, but from my understanding of what Paul was saying that's the approach that we're using in our health system in terms of walling off within the same record treatment notes, psychiatric treatment notes that are in essence a separate chart. It's really in the same chart, but that section is invisible to everyone except treating psychiatrists. Now, we happen to believe that ICD-9 coded problems and medications and med allergies that might refer to behavioral health issues actually belong in a shared problem and allergy list for safety issues, but that's why I preface my comments from the beginning it depends on what your desired outcome is.

Paul Egerman - eScription - CEO

... just decide -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I'm going to let Jodi jump in only because a detailed discussion of data segmentation is really not on the table for this call.

Jodi Daniel - ONC - Director Office of Policy & Research

I wanted to jump in and sort of echo that. Two things: One, Alison was about to jump in here to say that the next paper that they are working on is focused on data segmentation, so I imagine that this workgroup will be very interested in looking at that paper once it comes out. Perhaps the folks who are working on that paper may want to pick some of your brains in thinking this through.

But also, we are planning to look at sort of technical capabilities for protecting information, including data segmentation. It's something else that ONC is taking on, so there are a couple of things coming down the pike that will get into more detail on data segmentation, both from a policy and a technical perspective. We hope to have that conversation in this workgroup once we have a little more information to elaborate on and to provide background for that discussion.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. I mean that's very good to hear, Jodi. I think it would be helpful to the extent that it's possible to get a sense of the timing of the paper and other things that ONC maybe are working on that are related to that issue so that we can time our own deliberations and the issues that we're taking up accordingly just in terms of this ever evolving work plan.

Jodi Daniel - ONC - Director Office of Policy & Research

Yes. I think we're talking about a matter of months, just like two or three months for both of those activities that I mentioned. We don't have exact dates to give folks, so I don't want to commit to anything, but they're both actively being pursued and hopefully in the next couple of months, two or three months, we will have some more information for you all.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Terrific.

Peter Basch - MedStar Health - Medical Director

I had one other comment to make on Paul's first comment, which he apologized for, which was detecting a node of perhaps in the language favoring one form of health information exchange over another. I didn't read it that way, but I do feel that either the way that one thinks of health information exchange or the way that one asks in a survey to both providers and to patients and consumers about what exactly that means probably has colored a lot of survey data. In other words, if we had had this concept of NHIN Direct years ago when we started asking questions about how comfortable do you feel with your data being exchanged electronically, which is still a philosophic conception to most people, we may have had very different perceptions and views on this, so I think it's a very valid point.

Alison Rein – NCL – Assistant Director Food & Health Policy

Melissa will jump in as well if I don't adequately cover this but, Paul, it was not our intention certainly and I think what you've picked up on is just our inability to come up with better terms to try and describe having something where it's a little bit more discreet and manageable just because of the scale versus having something that seems to be a much bigger effort given that it's a network effort and involves a lot more players and therefore becomes, perhaps, more complex.

The mature was intended to reflect the types of information that they were exchanging, not necessarily the fact that they were networks because, quite honestly, there's a number of efforts that are trying to be networks that are not at all mature. Not to name names or anything, but I think they would actually admit that.

If you're picking up on a bias it was certainly not intentional, but I think it was perhaps our lack of ability to better capture that distinction with perhaps less provocative language. Melissa, do you want to add anything to that?

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

I think we actually struggled with this, Paul. I'm sure you can imagine the conversations. "Well, if we say complex is that better than sophisticated? What if we say really detailed? Is that better?" It didn't seem that we could really find words that didn't indicate something that we didn't want to indicate. So we do apologize. I even got out the thesaurus once, which, frankly, was not very helpful, but I do understand the sensitivity, because I thought it myself while I read through the paper.

Part of it is the NHIN Direct and the constant sort of changing of the landscape here, which was another of our problems and trying to capture something that lots of people have been talking about for a long time and that could change tomorrow. This is just a little anecdote. The very last day we had to change a sentence at the end of the paper because health reform was passed, so we had to figure out how to do that.

Alison Rein – NCL – Assistant Director Food & Health Policy

We had to put in a totally different example.

<u>Melissa Goldstein – Dept. of Health Policy – Associate Research Professor</u> Yes. Exactly.

Alison Rein – NCL – Assistant Director Food & Health Policy

It was a good problem to have, but we had to put in a different example.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

It was. It was good, but you know, I appreciate the comments. Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Hello, Alison and Melissa. As Melissa just pointed out, this has been the debate and the topic has been alive for quite a while. I think a couple of letters I'm sure you're going to consider as you prepare your segmentation report that the NCBHS letters of February 2008 and June 2006; those actually might be decent letters to help bring people up to speed on what's sort of been discussed in public testimony just to get the workgroup up to speed on what's been done in this area.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Paul, thank you for adding that. I think that's actually helpful. I noticed that a bunch of NCBHS' work was cited in the paper, but I think as we really get down to having conversations about where we think federal policy ought to be in this regard we'd need to have a very clear understanding of where the path that NCBHS has taken and what were the set of assumptions in play at the time. Just for example, I have always read both of those letters as applying pretty clearly to the NHIN and the conceptions of that are changing under the new administration versus what was envisioned to mean the NHIN in the Bush administration. So I definitely think it's worth exploring those and thinking about in what context they were presented at the time. I don't know if you all are reflecting on whether your recommendations are different now that there's NHIN Direct and NHIN Connect and different permutations of an NHIN that are not quite the network of networks approach that was the undergirding for the original NHIN.

Paul Egerman - eScription - CEO

I think that's a very wise point, Deven. I think to reiterate my prior point, I think it colors perception of the public, patients and providers, but also may subtly or even more dramatically change the types of recommendations that made sense when we were dealing with; I'll use a different term rather than mature; the big enchilada NHIN rather than other approaches to data exchange.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

The big enchilada?

Paul Egerman - eScription - CEO

Well, I don't know. If you like enchiladas that's a positive; if you don't it's pejorative, so there you go.

Deven McGraw - Center for Democracy & Technology - Director

Other folks who had questions for Alison and Melissa?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

Yes, I have a question. Did your study, and I haven't read it yet; it's on my shelf; address FDA informed consent or just the HIPAA consents and authorizations for privacy?

Alison Rein - NCL - Assistant Director Food & Health Policy

Melissa, I'm going to let you take that one.

Deven McGraw - Center for Democracy & Technology - Director

Uh-oh. Did we lose her? Did I get lost?

M

No, we can hear you.

Deven McGraw - Center for Democracy & Technology - Director

Okay. Thank you. Melissa, are you on the line still?

M

You might be lost, Deven, but we can hear you. I'm sorry. I couldn't resist.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Fair point. Fair point. We may have lost Melissa. Since I have read the paper, Dixie, it's actually dealing more so with how the different data exchanges have layered additional or not layered additional consent policies with respect to networks either that are state wide or within states as certain examples. So it does go into some detail about sort of what HIPAA does require. It doesn't touch on FDA because it doesn't go into research questions. Is there something I'm missing here?

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u>

Not informed consent like for treatment or -

Deven McGraw - Center for Democracy & Technology - Director

No. No. It deals with data consent and/or authorizations for data use and access, but not really focusing in on the research piece unless I skimmed over a section.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

I think maybe not in this conversation, but as we address as a workgroup consent, from a technology perspective if you're collecting consent for a particular treatment or from a particular patient a patient won't see much difference, nor would an electronic record system see much difference between giving someone permission to use their private data versus giving them permission to use their private data for research or giving them permission for using them in a research database for example or giving them consent to perform a particular test on them. I think we should look at this consent problem more generally than just focusing in completely on the HIPAA consent and authorizations, but rather when a patient is asked for permission to do something.

W

So I think that to the extent that we address that issue in the paper it is captured in the granularity for by purpose. So if you refer back to that slide a number of exchanges that are getting started say that we are exchanging this information for treatment or if it's part of an HIO and the data are flowing in some networked environment we will be accessing this information for treatment and we have the authority to use it for public health surveillance, but for right now we are not using it for certain other purposes. That doesn't mean that at some point there won't be a decision made or that there hasn't already been a decision made in some of these exchange entities to actually use the data for research purposes and they have varying ways of obtaining that consent from the subjects.

<u>Jodi Daniel - ONC - Director Office of Policy & Research</u>

I would say also as one clarifying point that the focus on this was about consent or authorization, permission choice regarding data use, whether for treatment or otherwise as opposed to consent or authorization or permissions of some sort for medical care or participation in clinical trial, that sort of thing.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

Yes. Yes. I get -

Jodi Daniel - ONC - Director Office of Policy & Research

So it's not necessarily limited to a HIPAA consent or authorization, but it was looking at permissions related to data use as opposed to permissions related to medical care.

Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences

All right. So in other words, like right now if a doctor, if a researcher is looking for prospects for a clinical trial they can legally come in and look in a database within a covered entity to do that kind of cohort analysis, but if, for example, a research network wanted to have several hospitals send data to a third, to a research database that's not allowed, but your study would have addressed the consent needed to do that.

Marianna Bledsoe – NIH – Deputy Associate Director

Yes. This is Marianna. I would just like to echo what Dixie's been saying here. I think we have to think broadly about this issue of consent and what this will mean for downstream uses ... research.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

It's Melissa. I'm not sure who I interrupted. I think I interrupted everybody. I could hear what was going on; I just couldn't get the *6 to un-mute me, so whenever you want me to jump in I'm here and I could hear everything that was going on. I just wanted to let you know.

Alison Rein – NCL – Assistant Director Food & Health Policy

I was just going to point out that we do have in our analysis of models, there is a section or an impact of models; there is a section that considers the impact on research of various approaches. However, I will caveat that by saying that we don't necessarily have a lot of evidence yet because we don't have a lot of different consent models as they've been applied to compare what impact they've had on research. So there is a GAO report that has some information and that's sourced in this paper. We definitely try to illuminate that as an important issue, but because we were covering so much ground with this we couldn't take a really, really deep dive in, so this wasn't necessarily intended to be a paper about the implications of consent models on research. It was certainly something that was important to highlight, an area for important consideration and possibly for future studies, but not necessarily as the technical term was raised, the whole enchilada.

(Overlapping voices.)

Deven McGraw - Center for Democracy & Technology - Director

Hold on. We have a lot of people talking at once.

<u>Dixie Baker - Science Applications Intl. Corp. - CTO, Health & Life Sciences</u>

Never mind. Can I just -

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

Can I just say something really quickly?

Deven McGraw - Center for Democracy & Technology - Director

Yes

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

One of the issues with going forward and looking at different types of consent is that consent means different things to different people. If you were talking to a group of bio ... they would immediately talk about informed consent and other people separate electronic health information exchange from that, but some people do not. Some people think informed consent should apply to that. We address it as consent to exchange of my health information.

If you then talk about consent to research it's a whole different level, so at this point the exchanges seem to be trying to involve any notion of a consent in them, so separation out of the concept, I entirely agree that consent to research should be included. It's just tricky to negotiate all of those different elements of consent.

Marianna Bledsoe - NIH - Deputy Associate Director

Yes. I just think that we have to keep in mind as we move forward that what we do or what we recommend with regard to consent for exchange of health information will have an impact on research and we have to sort of keep that in mind as we move forward.

I had a couple of questions, but I don't know if anybody else wanted to respond on some of this issue.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Why don't you go ahead, Marianna?

Marianna Bledsoe - NIH - Deputy Associate Director

I had a couple of questions. One is in terms of the stakeholders' perspectives; and I apologize I got through about half of this paper; I didn't get through all of it; can you just describe sort of who the populations were that were included in the surveys? Were they general public? Were they patients with disease? Can you just briefly summarize?

Alison Rein – NCL – Assistant Director Food & Health Policy

Just to clarify, we did not do primary research on the general public. We actually cite different other efforts to elicit values, preferences, views from those types of people. I suspect, because we cite a number of different surveys and focus groups, that there would be a range, but I would have to go back to the source documents to be able to tell you what the demographic characteristics were of those populations.

Marianna Bledsoe - NIH - Deputy Associate Director

Okay. Yes, because I did see the citations there and I didn't have a chance to look at them, but that would be useful to know, I think, sort of what was the basis for the conclusions drawn in those studies.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I would point out I don't know if people saw the notice that was sent out I believe the end of last week, but it looks like there's going to be another major survey done about specifically consumer or the public's perceptions of health information exchange and so we will have another bolus of data coming in to build on this, but we referenced many of the surveys and focus groups that have been referenced previously on this issue I'm sure.

<u>Marianna Bledsoe – NIH – Deputy Associate Director</u>

I also had another question about the evidence base here. I think it will be important as we move forward to develop better evidence for some of these models in terms of their impact on healthcare and other issues. Do you know of any efforts under way to track that?

Alison Rein – NCL – Assistant Director Food & Health Policy

Well, I know that there are a number of different efforts that are being announced and embarking right now through the HITECH provisions, but I don't think that they're specifically tasked with looking at the issue of consent. I do know, however, that many, like the Beacon community for example, will probably be taking different approaches to the consumer engagement and exchange component and so there you will have the opportunity to reflect back and see what the implications were for the consent approach that

they took because obviously the key with the Beacon communities is that these are already IT advanced, HIE advanced communities and the expectation is they will become even more so and will have to incorporate this apparatus in order to do what they've set out to do over the course of the next, I think is it two or three years.

Marianna Bledsoe - NIH - Deputy Associate Director

Yes. I mean it seems like there was a window of opportunity here as those efforts move forward to develop some questions prospectively to help get at the impact issue.

<u>Alison Rein – NCL – Assistant Director Food & Health Policy</u>

It's interesting. I am sure that there is going to be a significant evaluation component on all of those and I am not the entity involved in that evaluation, but I do think you raise a really important point and so perhaps this workgroup would be in a good position to inform the work of that evaluation body or bodies if there happen to be multiples.

Deven McGraw - Center for Democracy & Technology - Director

Yes, I clued in on that as well, Marianna and Alison; that this notion that we have a plethora of different models out there, not just with respect to patient consent, but also with respect to data use policies and for what purposes are data being exchanged and who's participating and just a real richness of information that if we don't try to systematically look at what's most effective, both in terms of achieving greater meaningful use outcomes, as well as building public trust, we will have really squandered a tremendous opportunity and I hope we won't. I think it's a good idea that we think about that even as we're coming up with our own recommendations, both with respect to consent and as well with respect to other policies regarding data use.

Marianna Bledsoe - NIH - Deputy Associate Director

I couldn't agree more.

Deven McGraw - Center for Democracy & Technology - Director

One of the questions that I had, I have had a chance to read through the paper once and I was really struck by a number of things, one of which is the extent to which consumer education and greater effort by the HIE to sort of really do meaningful outreach to consumers to explain to them what was going on, the impact that that had with respect to participation. Now, it's a bit of an incomplete picture, because it wasn't a more robust study of sort of satisfaction and outcomes, etc., but it seemed at least from the examples in the paper, that the entities that had the resources and took the time to do some public education had greater success rates, greater participation rates, particularly with respect to consumers whether it was opt-in or opt-out.

Peter Basch - MedStar Health - Medical Director

Deven, I think that's a great point and I read through most of the study and felt the same way. I think Massachusetts and Rhode Island were examples where there were broader educational efforts. I would still contend that to most of the public even the term health information exchange is not well understood and might even be a frightening term that conveys putting information up on the Internet and has nothing to do with what health information exchange is.

I apologize for my rudeness to Melissa and Alison by not starting out with my first comment and saying hello and thank you for a wonderful paper. It's really a terrific paper, so thank you for doing this.

Alison Rein - NCL - Assistant Director Food & Health Policy

Thank you, Peter.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

Thank you, Peter.

Deven McGraw - Center for Democracy & Technology - Director

Did others have any particular questions or even want to start suggesting some issues to place on the table for our next call? Because that will be my task is to sort of start working up some framing that can try to move us forward.

I mean I will say the other thing that really struck me in reading the paper is, again, given the plethora of models what would national policy best look like in this regard given that there is still a lot of unknown about which models are successful and a huge variation in the way it's been applied. I'm struggling with that myself.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Maybe Melissa and Alison can answer this: I wonder if some of the diversity, well, some of it's the lack of a technical framework for health information exchange, but another is the lack of anywhere close to a common policy framework for health information exchange. I wonder what part of the diversity and the policies and the procedures are due to the lack of the policy framework. The reason I ask that is if a lot of it is to overcome the diversity in the policies then I wonder if a national policy, at least a floor, could help that. Do you see where I'm headed?

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

Paul, we included a section called Methods of Policy Recommendations towards the end of the paper, which basically is a march through of the ways that we thought of that different policies might be changed on the federal level, on the state level, through voluntary measures at either the federal level or the state level and what it might mean for different models that are already in existence because that's one of the big problems, right? You change something now. You've got so many people that have already been building these things, some of them for a very long time and you establish a floor. If that floor happens to be higher than other exchanges are actually operating then they have to change or they're grandfathered and then you have all of that mess, right?

So we're hoping that section will help you guys and others think through ways that we might actually change policy if we decide and conform policy or deal within the existing structure, but try to make it easier for versioning exchanges and ourselves to understand what's going on. It can be done in a variety of different ways and some of them are much more drastic, but also much more effective you might think if you want one particular policy. Some of them take much longer time and a whole lot of negotiation, but actually can sort of bring people to the table and hopefully reach, if not consensus, some sort of mutual, almost happiness.

Alison Rein – NCL – Assistant Director Food & Health Policy

While I think reasonable people could disagree one of the points of findings on our slide was that the architecture of your exchange has some significant implications for the policies that you would undertake, so partly for this effort and partly on another project I'm looking at a lot of consent decisions made in international examples, but they've come much closer generally speaking to articulating their vision of what type of architecture they want to have for exchange. I think if you want to move in that direction then you would apply certain policies and if you don't want to move in that direction you would apply some other policies, but it's really, really difficult to talk about implementing policies without having a better understanding of where you want to be. So I'm not here to tell you where you want to be, but I think that

that, in my mind, is part of what you guys are tasked with and I think that's really if I came away with like a big ah-ha from this experience that is it or one of the ten.

M

A common theme to what is privacy or the NHIN technology or the meaningful use quality and outcome is that I think the inconsistency and the conflicts amongst policy even perhaps more than technology infrastructure impedes quality, health costs and privacy. So is that an assumption we're willing to work on? If that's true, are we willing to try to advance a more common policy agenda?

Kathleen Connor - Microsoft Health Solutions - Principal Program Manager

I would prefer that we look at what kinds of technologies are out there today to deal with differing policies across jurisdictions because that is an approach that has been undertaken in other nations and see if there is some capacity to actually allow some differences and yet do policy bridging so that different jurisdictions can have their own autonomy rather than just immediately jump – it may be even a case that's a convergence on policy is what has to happen at the end of the day, but I would prefer if we also look at alternatives as well.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

Another point that I'll raise just from international example is that many have highlighted that it really also depends on how aggressive you want to be in what you exchange, so there are a lot of examples where the trade off of being highly directive at the top is that you just start with one or two things and get that done. People in those places will acknowledge that you can do a lot more perhaps on a smaller scale. It just depends on where you think the ... of that smaller scale might be, but I'm sorry to say that it's like really that complicated, but the more we got into the paper the more we realized it's really that complicated.

<u>Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences</u> Guess what? It's going to get worse.

<u>Melissa Goldstein – Dept. of Health Policy – Associate Research Professor</u> I know.

M

The word is better, not worse.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

More fun. The bigger enchilada.

W

The bigger enchilada.

Paul Egerman - eScription - CEO

I think the word you wanted was sophisticated.

Melissa Goldstein - Dept. of Health Policy - Associate Research Professor

That's exactly the word I wanted.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

From an enchilada to a burrito. All right. Are there other folks, who haven't had a chance to ask questions of our authors? Okay.

Why don't we prepare? If nobody else has any comments, again, we have yet another call scheduled for April 8th. I think that actually may be our last call before our Policy Committee meeting, so we'll have a lot to get in order. Does anybody have any further remarks they want to make before we open up the lines for public comment?

Okay. Hearing none, Judy?

Judy Sparrow – Office of the National Coordinator – Executive Director

Sure. Operator, would you like to see if the public has any comment to make, please?

Operator

We do not have any public comments.

Judy Sparrow - Office of the National Coordinator - Executive Director

Great. Thank you. Deven, back to you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay. Terrific. If folks can remember; Peter, I already got your comments; thank you very much; to send me –

Operator

Excuse me. This is the operator. I'm sorry to interrupt. Someone just queued in for a comment. Should we take them?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. Yes. Please.

Operator

Okay. Please proceed with your comment, sir.

W

This is I'm calling you from California Health & Human Services Agency. I just have a request for Deven McGraw. I wanted to know where would the material that she had today be available. We had a technical difficulty and I couldn't see the slides of her presentation.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Oh, dear.

W

Yes

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. They weren't my slides, but that's okay. Judy, are the materials on the Web site?

<u>Judy Sparrow - Office of the National Coordinator - Executive Director</u>

Yes, they are on the ONC Web site if you go there, healthit.hhs.gov/federaladvisorycommittee.

W

Okay. Will do. Thank you.

Deven McGraw - Center for Democracy & Technology - Director

Okay. That one was easy. Okay. Don't forget to send me your comments on the EHR module approach; that's when privacy and security certification criteria apply to EHR models is the sort of top-line of the page. Send that to me by the end of the month, March 31st, which is next Wednesday.

Also, feel free to, as you finally are able to read through this paper, share your thoughts with me as I sit down with staff and my co-chair, Rachel to come up with a more firm agenda for the discussion on the 8th.

Jodi Daniel - ONC - Director Office of Policy & Research

Can I jump in for a second, Deven? One other thought is; Alison is here with me, so we were just talking on mute; but if folks, as they read this, have further questions that they want to ask of Alison or Melissa do you want to collect those and we can package them and send them out or what do you think would be the best approach? I think it would be good because they won't be on the next call to give us feedback.

Deven McGraw - Center for Democracy & Technology - Director

Right. Yes, I think that does make sense, Jodi. If they want to send me any additional questions we can package them all up together and get some responses, so if in reading it you have questions for the authors, send those too.

Okay. If there's nothing else then we get a little bit more of a break this time. Thank you, everyone, for your time. Read the paper and we'll see you soon.

W

All right. Thank you. Good-bye.